



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

ML

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/582,442	06/26/00	NISHIDA	H 1110-0271P

002292 HM12/0112
BIRCH STEWART KOLASCH & BIRCH
8110 GATEHOUSE ROAD
SUITE 500 EAST
FALLS CHURCH, VA 22042

EXAMINER

TRUONG, T

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED:

01/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/582,442

Applicant(s)

NISHIDA ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- Th MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 10, and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11-14, and 16 is/are rejected.
- 7) ☒ Claim(s) 6-9 is/are objected to.
- 8) ☐ Claims 1 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6-26-00.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Applicant's election of Group I in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). However, applicant's request to include species with 2 of G₁ to G₃ are nitrogen atoms seems reasonable, and thus, group I is revised as in applicant's amendment.

Improper Markush: Claims 1- 5, 11-14, and 16 are rejected on the ground of Judicially Created Doctrine as being drawn to Improper Markush Groups. **In re Harnisch**, 206 USPQ 300. The recited compounds, while possessing a common utility present a variable core, and thus the Markush Groups represented by the terms "X", "Y", and "G₁" to "G₄" render the claims clearly improper.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, and 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. In claims 1 and 2, the term “cyclic amino group” seems to mean a nitrogen containing heterocycle. However, in the specification, said term includes even a morpholine. Thus, it is unclear as to what constitutes a “cyclic amino group”.
- b. In claims 1 and 2, the limitation “lower alkoxy” is recited twice.
- c. In claim 1, the limitation, “each R₂, ..., R₉ forms a carbonyl group...”, is unclear as to whether an oxo group is meant or a ketone group is attached to the ring where said variables attached. If an oxo group is meant, then there will be a possible of 4 oxo groups on said ring which does not seem to exist.
- d. Claims 11-14 are substantial duplicates because they recite the same composition containing compounds of claim 1. Note, different uses recited in claims 12-14 are considered as preambles which do not have patentable weight.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 11-14, and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds with R₁ is hydrogen, does not reasonably provide enablement for compounds with R₁ as a “cyclic amino group”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

Art Unit: 1624

connected, to make and use the invention commensurate in scope with these claims. The definition of said term is so vague in the disclosure that one simply cannot ascertain what other groups are considered as a "cyclic amino group" besides those listed in the disclosure. Furthermore, in the generic teaching, the ring containing G₁-G₄ comes as a R₁ substituted ring (e.g. formula XXX on page 86). Thus, when R₁ is a "cyclic amino group", one does not know how to obtain the starting material for formula XXX. Therefore, undue experimentation is inevitable if one skilled in the art were to make and use the claimed compounds with such a substituent. Regarding enablement for chemical cases, the M.P.E.P. explicitly states that:

...in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F. 2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most **chemical reactions** and **physiological activity**, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)... See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ 2d 1438, 1445 (Fed. Cir. 1991). This is because it is **not obvious** from the disclosure of one species, what other species will work. {M.P.E.P. 2164.03}

Also, as has been ruled by the court in *Genetech Inc. v. Novo Nordisk*, failure to disclose any specific starting material or any condition for preparation constitutes lack of enablement. Thus, relying on the knowledge of one skilled in the art cannot cure such deficiency in enablement (*Genetech Inc. v. Novo Nordisk*, 108 F.3d 1361, 42 USPQ 2d 1001 (Fed. Cir. 1997)).

Claim Objections

Claims 6-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Information Disclosure Statement

The information disclosure statement filed on 11-09-2000 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The IDS filed on 6-26-2000 is considered to the extent of the examiner's understanding. In particular, ^{only} ~~on~~ chemical structures in JP-63-23874 is considered. Said Japanese patent appears to read on the non-elected subject matter.

There are two WO patents that seem to read on the instant invention. They are WO 99/06395 and WO 99/40075. However, because their publication dates do not antedate the filing date of the instant application, they are not competent prior arts. Nevertheless, applicant is urged to review these references thoroughly as said WO patents have corresponding US applications.

Art Unit: 1624

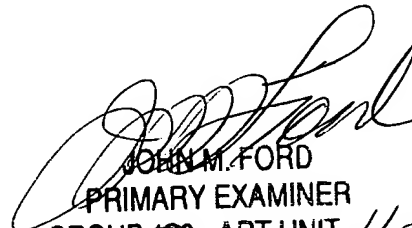
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom (or Tam) N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on Monday through Friday from 9:30 a.m. to 6:00 p.m.

The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong / 1-10-01



JOHN M. FORD
PRIMARY EXAMINER
GROUP 420 - ART UNIT 1624